REMARKS

Continued Examination Under 37 CFR 1.114

Applicant appreciates the Examiner's acknowledgement that the present application is eligible for continued examination under 37 C.F.R. 1.114 and that the appropriate fee was timely paid for the same. Applicant also appreciates the Examiner's withdrawal of the finality of the previous Office Action and entrance of Applicant's submission filed on November 26, 2008.

Withdrawn Rejections

Applicant appreciates the Examiner's acknowledgement that all rejections not specifically reiterated in the most-recent Office Action have been withdrawn.

Rejection of Claims 32-34 under 35 U.S.C. 112, First Paragraph

The Examiner rejected claims 32-34 under 35 U.S.C. 112, first paragraph, for the reasons of record. Specifically the Examiner stated that the Applicant has not disclosed how one skilled in the art can establish with a high-level of predictability if the lipid phosphatase activity indicates a disease-caused alteration of lipid phosphatase or is due to obesity, age, temperature or disease.

Thus, Applicant respectfully submits that the instant specification provides sufficient examples and guidance related to As such, Applicant respectfully requests withdrawal of the rejection of claims 32-34 under 35 U.S.C. 112, first paragraph.

Rejection of Claims 1-4, 7, 8, 10-13, 32-34 and 38 under 35 U.S.C. 112, Second Paragraph

The Examiner rejected claims 1-4, 7, 8, 10-13, 32-34 and 38 under U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention for the reasons of record. In light of the same, Applicant has amended independent claims 1 and 32 to more particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Such

amendments have been made without prejudice or disclaimer of the subject matter therein and were made solely for the sake of moving prosecution forward.

Support for the amendments can be found on p. 5, paragraph 26 and throughout the application. For example, the Examiner has stated that, "it is unclear how a change in concentration of the lipid product is determined," in claim 1 and p. 5 states that, "the assay can be any of a number of assay types, but is preferably a plate-based assay." The specification goes on to list enzyme linked immunosorbent assays, amplified luminescence proximity homogenous assays and fluorogenic assays, such as fluorescence polarization, fluorescence resonance energy transfer or time-resolved fluorescence resonance energy transfer. One skilled in the art would be familiar with each of these assay types. Additionally, Applicant amended claim 32 to remove the second reference to the term, "disease." In light of the amendments made to claim 1, Applicant respectfully asserts that claim 38 now particularly points out and distinctly claims the subject matter the Applicant regards as its invention.

In light of the above comments, Applicant respectfully requests withdrawal of the rejection of claims 1-4, 7, 8, 10-13, 32-34 and 38 under U.S.C. 112, second paragraph.

Rejection of Claims 1-4, 7, 10, 11, 14, 32-34 and 38 under 35 U.S.C. 102(a)

The Examiner rejected claims 1-4, 7, 10, 11, 14, 32-34 and 38 under 35 U.S.C. 102(a) as being anticipated by Dowler for the reasons of record. Applicant respectfully traverses this rejection.

Initially, Applicant respectfully asserts that the office action mischaracterizes the disclosures of Dowler. The reference teaches a method where a substrate lipid is incubated with an appropriate enzyme in the presence of a PH domain fused green fluorescent protein (see p. 131, lines 24-28). In no way does Dowler disclose exposing a lipid detector protein to a solution containing a substrate lipid and lipid phosphatase. Additionally, Dowler does not mention PI(4,5)P2, PI(5)P, or PI and specifically does not disclose binding of PI(3,4,5)P3.

Applicants respectfully point out that in order to establish a prima facie case of obviousness, it must be shown that each and every one of the claim limitations was suggested or taught by the prior art being relied on. *In re Royka,* 490 F.2d 981, 180 USPQ 580 (CCPA

1974). Additionally, "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

Applicants respectfully submit that the Examiner has not met this burden. Specifically, Dowler does not disclose exposing a lipid detector protein to a solution containing a substrate lipid and lipid phosphatase or mention PI(4,5)P2, PI(5)P, or PI and specifically does not disclose binding of PI(3,4,5)P3. Additionally, when an independent claim is deemed nonobvious under 35 U.S.C. 103(a), then all claims depending therefrom are nonobvious as well. *In re Fine*, 837 F.2d 1071, 5 USPQ 2d 1596 (Fed Cir. 1088). Applicants assert that in view of the foregoing, Applicant respectfully requests withdrawal of the rejection of claims 1-4, 7, 10, 11, 14, 32-34 and 38 under 35 U.S.C. 102(a).

Rejection of Claim 8 under 35 U.S.C. 103(a)

The Examiner has rejected claim 8 under 35 U.S.C. 103(a) over Dowler et al. in view of Goueli et al. (U.S. 6,720,162) ("Goueli") for the reasons of record.

As mentioned above, Applicant respectfully asserts that the office action mischaracterizes the disclosures of Dowler. The reference teaches a method where a substrate lipid is incubated with an appropriate enzyme in the presence of a PH domain fused green fluorescent protein (see p. 131, lines 24-28) In no way does Dowler disclose exposing a lipid detector protein to a solution containing a substrate lipid and lipid phosphatase. Additionally, Dowler does not mention PI(4,5)P2, PI(5)P, or PI and specifically does not disclose binding of PI(3,4,5)P3.

Applicant also asserts that the Examiner has mischaracterized Goueli. The Goueli reference describes lipid kinase and phosphatase assays where the lipid kinase and phosphatase assays where the lipid substrate is modified, i.e. biotinylated (or immobilized), and is detected radioactively which requires a separation step. The liquid phase assay in Goueli column 3 is also liquid during the enzymatic conversion, but detection still requires radioactivity and separation. Finally, Goueli also discloses the measurement of phosphatase activity by quantifying free phosphate. In contrast, the claimed lipid phosphatase assays

always detect the lipid product, use nonbiotinylated/mobile substrates and do not require radioactivity or a separation step.

Therefore, neither Dowler nor Goueli discloses all of the limitations of the claims at hand as required to make a case of obviousness. Additionally, the differences between the claimed invention and Goueli are of such a nature that one would not have had a reasonable expectation of success in using Goueli as a reference from which to learn how to conduct the claimed invention, making it unavailable as an obviousness reference.

In view of the foregoing remarks, Applicant respectfully requests withdrawal of the Examiner's rejections of claim 8 under 35 U.S.C. 103(a).

Rejection of Claims 12 and 13 under 35 U.S.C. 103(a)

The Examiner has rejected claims 12 and 13 under 35 U.S.C. 103(a) over Dowler et al. in view of Taylor (U.S. Analytical Biochemistry, 295, 122-126, 2001) ("Taylor") for the reasons of record.

As mentioned above, Applicant respectfully again asserts that the office action mischaracterizes the disclosures of Dowler for a variety of reasons. Along with the reasons stated above, Applicant also disagrees with the Examiner's statement that, "Dowler is generic with respect to the lipid phosphatases to be determined," as the assay of Dowler is very different from the assay of the present invention. One would not have had a reasonable expectation of success in using Dowler as a reference from which to learn how to practice the claimed invention, making it unavailable as an obviousness reference.

With that said, Applicant agrees with the Examiner's statement that, "Dowler differs from the instant invention in failing to teach the lipid phosphatase is myotubularin or PTEN." Applicant also agrees with the Examiner in that, "Dowler also fails to specifically state that the sample has additional lipids."

Therefore, neither Dowler nor Taylor discloses all of the limitations of the claims at hand as required to make a case of obviousness. Additionally, the differences between the claimed invention and the two references are of such a nature that one would not have had a reasonable expectation of success in using them from which to learn how to conduct the claimed invention, making it unavailable as an obviousness reference.

Provisional Rejection of Claims 1-4, 7, 8, 10-12 and 14 On Ground Of Non-Statutory Obviousness-Type Double Patenting

The Examiner has provisionally rejected claims 1-4, 7, 8, 10-12 and 14 on the ground of non-statutory obviousness-type double-patenting. Applicant will address this issue by filing a terminal disclaimer, should the need arise.

Concluding Remarks

In view of the foregoing, Applicant respectfully submits that all rejections under record have been overcome. Accordingly, Applicant believes that Claims 1-4, 7-8, 10-15, 32-34 and 38 are now in a condition for allowance.

If the Examiner notes any further matters which would be expedited by a telephonic interview, she is requested to contact Dr. Jennifer M. McCallum at the telephone number listed below.

Respectfully submitted,

Jennifer M. McCallum, Ph.D., Esq. Date July 7, 2009

Reg. No. 52,492
Customer No. 36234
The McCallum Law Firm, P.C.
P.O. Box 929 / 685 Briggs Street
Erie, CO 80516
Telephone: 303-828-0655
Fax: 303-828-2938
e-mail: administration@mccallumlaw.net